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| 10/755,038 | 01/09/2004 | Avram Reuben Gold | 2111-040037 | 7887 |

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| EXAMINER |
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LEWIS, AARON J

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| ART UNIT | PAPER NUMBER |
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3743

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/755,038 | Applicant(s) GOLD, AVRAM REUBEN | |
| | Examiner AARON J. LEWIS | Art Unit 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
4a) Of the above claim(s) 2,3,13,14 and 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-12 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f). In the instant specification on page 9, PCT/US01/01874 (WO 01/52928) and on page 10, PCT/US98/21864 (WO 99/20339).

2. The use of the trademarks REMstar®, Solo®, BiPAP®, Virtuoso®, PAV® have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1, 4-12, 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating the particular functional somatic syndrome of fibromyalgia, UARS and OSA/H, does not reasonably provide enablement for treating other functional somatic syndromes such as chronic fatigue syndrome, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, Gulf War syndrome, premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, chronic whiplash, restless leg/periodic limb movement syndrome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant has provided disclosure of identifying different patients, each suffering from one of fibromyalgia, UARS and OSA/H; a connection between fibromyalgia and UARS and OSA/H by showing common symptoms; and then provided a clinical example of treating patients suffering from fibromyalgia with positive airway pressure therapy; however, there is no disclosed clinical connection between any of the additional recited functional somatic syndromes and UARS or OSA/H that would provide one of ordinary skill with sufficient information to make and use the instant invention without undue experimentation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1,6,7,11,12,17,18 are rejected under 35 U.S.C. 102(e) as being anticipated by Pantino ('910).

As to claim 1, Pantino discloses a method of treating functional somatic syndromes comprising the steps of: identifying a patient as having a functional somatic syndrome (e.g. temporomandibular joint syndrome, a known functional somatic syndrome at col.8, lines 50-51); and treating such a patient with an airway stabilization technique (fig.1).

As to claim 6, Pantino (col.5, lines 25-27 and col.8, line 50-51) discloses identifying a patient as having temporomandibular joint pain which is a symptom of a known functional somatic syndrome, temporomandibular joint syndrome.

As to claim 7, Pantino discloses upper (13) and lower (12) members of the airway stabilizer are of minimal thickness such that airflow and oral architecture are minimally impacted. Inherent in adjusting the airway stabilizer to fit a particular patient's mouth is making sure airflow is minimally impacted by monitoring for any airflow limitation including an inspiratory airflow limitation.

As to claim 11, Pantino as discussed above with respect to claim 1 also discloses the functional somatic syndrome of temporomandibular joint syndrome (col.5, lines 25-27 and col.8, line 50-51).

Claim 12 is substantially equivalent in scope to claim 1 and is anticipated by Pantino for the reasons set forth above with respect to claim 1.

As to claim 17, Pantino (col.5, lines 25-27 and col.8, line 50-51) discloses identifying a patient as having temporomandibular joint pain which is a symptom of a known functional somatic syndrome, temporomandibular joint syndrome.

As to claim 18, Pantino discloses upper (13) and lower (12) members of the airway stabilizer are of minimal thickness such that airflow and oral architecture are minimally impacted. Inherent in adjusting the airway stabilizer to fit a particular patient's mouth is making sure airflow is minimally impacted by monitoring for any airflow limitation including an inspiratory airflow limitation.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4,5,15,16, are rejected under 35 U.S.C. 103(a) as being unpatentable over Pantino ('910) in view of Thornton ('048).

The difference between Pantino and claim 4 is stabilizing a patient's airway with positive airway pressure therapy.

Thornton teaches a method of stabilizing a patient's airway by employing a combination of positive airway pressure therapy and a mechanical stabilizer (fig.1a). the advantage of using both positive airway therapy with a mechanical stabilizer is to provide a means for adjusting upper and lower teeth arches thereby increasing the opening of the user's breathing passageway to increase the effectiveness of treatments

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for breathing disorders such as OSA while remaining comfortable for the patient (col.2, line 58-col.3, line 10).

It would have been obvious to modify the method of treating temporomandibular joint syndrome of Pantino to include positive airway pressure therapy in combination with a mechanical stabilizer because it would have provided a means for adjusting upper and lower teeth arches thereby increasing the opening of the user's breathing passageway to increase the effectiveness of treatments for breathing disorders such as OSA while remaining comfortable for the patient as taught by Thornton.

As to claim 5, Thornton teaches the positive airway therapy is CPAP (88).

Claim 15 is substantially equivalent in scope to claim 4 and is included in Pantino as modified by Thornton for the reasons set forth above with respect to claim 4.

As to claim 16, Thornton teaches the positive airway therapy is CPAP (88).

9. Claims 8,9,19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pantino ('910) in view of Thornton ('048) as applied to claims 4,5,15,16 above, and further in view of Kowallik et al.('766).

The difference between Pantino as modified by Thornton and claim 8 is the step of categorizing a patient who has an inspiratory airflow during sleep of approximately 51-100% of waking levels as an upper airway resistance syndrome patient.

Kowallik et al. (col.5, lines 12-20; col.6, lines 10-44 and col.8, lines 7-11) teach the step of categorizing a patient who has an inspiratory airflow during sleep of approximately fifty-one to one-hundred percent of waking levels as an upper airway resistance syndrome (UARS) patient for the purpose of detecting breathing patterns

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and to help a clinician differentiate between a patient with UARS and one suffering from OSA (col.3, lines 53-60).

It would have been obvious to further modify Pantino to include means for categorizing patients by type of respiratory disorder because it would have provided a means for detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA as taught by Kowallik et al..

Claim 19 is substantially equivalent in scope to claim 8 and is included in Pantino as further modified by Kowallik et al. for the reasons set forth above with respect to claim 8.

As to claims 9,20, Kowallik et al. (col.5,lines 12-20 and col.6, lines 10-62) teach categorizing a patient who has an inspiratory airflow during sleep of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pantino ('910) in view of Bennett ('686).

The difference between Pantino and claim 10 is observing alpha-delta sleep of such a patient to diagnose the functional somatic syndrome.

Bennett (col.1, lines 38-51) teaches observing alpha-delta sleep of such a patient to aid in diagnosing the functional somatic syndrome fibromyalgia.

It would have been obvious to modify Pantino to include monitoring patients for alpha-delta sleep to diagnose a functional somatic syndrome as taught by Bennett because it would have aided in the diagnosing more serious illnesses which may also exhibit sleep disorder symptoms as taught by Bennett.

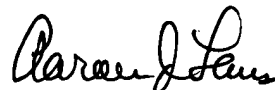
Response to Arguments

11. Applicant's arguments with respect to claims 1,4-12,15-20 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
May 10, 2006